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PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/731,108	12/10/2003	Todd A. Werpy	13872-B	8899	
21567	7590 02/21/20		EXAMINER		
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601 W. FIRST SPOKANE, Y	l AVENUE, SUITE WA 99201	300	ART UNIT	ART UNIT PAPER NUMBER	
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DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

A 5	Application No.	Applicant(s)		
	10/731,108	WERPY ET AL.		
Office Action Summary	Examiner	Art Unit		
	Robert Shiao	1626		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED	. ely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
Responsive to communication(s) filed on <u>respo</u> This action is FINAL . 2b) ☑ This Since this application is in condition for allowant closed in accordance with the practice under E.	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) Claim(s) 1-15 and 45-51 is/are pending in the a 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-15 and 45-51 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	vn from consideration.			
 9) The specification is objected to by the Examiner 10) The drawing(s) filed on 10 December 2003 is/ar Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner 	re: a) \square accepted or b) \square objected or by accepted or by acceptance. See on is required if the drawing(s) is objection.	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 06/14/04, 12/10/04.	4) Interview Summary (Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:	te		

DETAILED ACTION

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1. This application claims priority of the provisional application: 60/435,469 with a filing date 12/20/2002.

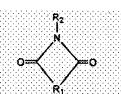
2. Amendment of claim 1, cancellation of claims 16-44, and addition of claims 45-51 in the amendment filed on December 21, 2005, is acknowledged. No new matter is found. Claims 1-15 and 45-51 are pending in the application. Since the newly added claims 45-51 are commensurate with the scope of the invention, therefore, claims 1-15 and 45-51 are prosecuted in the case.

Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on December 10, 2004, or June 14, 2004, have been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. Applicant's election without traverse of Group I claims 1-15, in part, in the reply filed on December 21, 2005, is acknowledged. A elected a compound of formula (I),



wherein the variable R₁ contains two carbon atoms, and the variable

R₂ contains a single carbon atom, is also acknowledged.

Claims 1-15 and 45-51 are pending in the application. The scope of the

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invention of the elected subject matter is as follows.

Claims 1- 15 and 45-51, in part, drawn to processes of making compounds of

formula (B), (C), (D), or (E), or formula (I), wherein the variable R_1 containing two or three carbon atoms thereof.

Claims 1-15 and 45-51, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-15 and 45-51, in part, <u>not</u> embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 45-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, page 3, line 1, recites the limitation "comprising one or more additional components", is ambiguous and indefinite. It is unclear what one or more additional components are. Are they compounds of formula (B), (C), (D) or (E)? Dependent claims 2-15 and 45-51 of claim 1 are also rejected along with claim 1 under 35

U.S.C. 112, second paragraph. Clarification is required, see pages 12-14 of the specification.

Claim Rejections - 35 USC § 103

- **6**. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

7. Claims 1-15 and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werpy et al. US 6,603,021; or over Werpy et al. US 6,706,893; or over Werpy et al. US 6,632,951; or over Werpy et al. US 6,670,483. Werpy et al. '021, '893, '951, or '483 is 102 (e) reference.

Applicants claim a process of making pyrrolidones compounds of formula

, wherein the variable the variable R_1 containing two carbon atoms, the variable R_2 comprises an alkyl group. The processes are operated by reacting

compounds of formula (A), (i.e., succinamic acid), with ammonia to

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form compounds of the formula,

, and hydrogenation in the presence of

catalyst to from the final products

see claims 1 and 12.

Dependent claims 2-11, 13-15, and 45-51 of claim 1 further limit the scope of variables R_1 - R_2 of starting materials, catalyst, by products, or reaction conditions. Dependent claim 45-47 of claim 1 further limit the scope of initial compounds of formula

Determination of the scope and content of the prior art (MPEP §2141.01)

Werpy et al. '021, '893, '951, or '483 independently discloses a process of

3, 3, 8, R₂

making pyrrolidones compounds of formula (C),

, wherein the variables

R₁, R₂, R₃, R₄, and R₅ independently represents hydrogen or C₁₋₆ alkyl. Werpy et al.

processes are operated by reacting compounds of formula (B),

. with

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ammonia to form compounds of formula (A),

and hydrogenation in the

presence of catalyst to from the final products. Werpy et al. processes have been disclosed in columns 19-20 of Werpy et al. '021, or columns 18-20 of Werpy et al. '893, or columns 20-21 of Werpy et al. '951, or column 20 of Werpy et al. '483.

<u>Determination of the difference between the prior art and the claims (MPEP §2141.02)</u>

The difference between instant claims and Werpy et al. processes is that the variable R_1 contains two or three carbon atoms, while Werpy et al. contain two carbon atoms. It is noted that the starting material compounds of formula (B) of Werpy et al. '951 is in a mixture resulting from fermentation.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 1-15 and 45-51 prima facie obvious because one would be motivated to employ the processes of Werpy et al. to obtain instant claimed processes, wherein compounds of formula (A),

(i.e., succinamic acid), with ammonia to form compounds of the

formula, , and hydrogenation in the presence of catalyst to from the final

The motivation to make the claimed processes derives from the expectation that the instant claimed processes derived from known Werpy et al. processes would possess similar yields to that which is claimed in the reference.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-15 and 45-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of Werpy et al. US 6,603,021; or over claims 1-3 of Werpy et al. US 6,706,893; or over claims 1-2 of Werpy et al. US 6,632,951; or over claims 1-4 of Werpy et al. US 6,670,483. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a process of making pyrrolidones compounds of formula

variable R_2 comprises an alkyl group. The processes are operated by reacting

form compounds of the formula,

, and hydrogenation in the presence of

catalyst to from the final products

, see claims 1 and 12.

Dependent claims 2-11, 13-15, and 45-51 of claim 1 further limit the scope of variables R_1 - R_2 of starting materials, catalyst, by products, or reaction conditions. Dependent claim 45-47 of claim 1 further limit the scope of initial compounds of formula

(A), i.e., which is a fermentation product.

Werpy et al. '021, '893, '951, or '483 independently claims a process of making

rrolidones compounds of formula (C)

pyrrolidones compounds of formula (C), wherein the variables R_1 , R_2 ,

 $R_3,\,R_4$, and R_5 independently represents hydrogen or $C_{1\text{-}6}\,\text{alkyl}.$ Werpy et al. processes

R. 23 X R. Y

are operated by reacting compounds of formula (B),

, with ammonia to

form compounds of formula (A),

and hydrogenation in the presence of

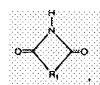


catalyst to from the final products

The difference between instant claims and Werpy et al. processes is that the variable R₁ contains two or three carbon atoms, while Werpy et al. contain two carbon atoms. It is noted that the starting material compounds of formula (B) of Werpy et al. '951 is in a mixture resulting from fermentation.

One having ordinary skill in the art would find the claims 1-15 and 45-51 prima facie obvious because one would be motivated to employ the processes of Werpy et al. to obtain instant claimed processes, wherein compounds of formula (A),

(i.e., succinamic acid), with ammonia to form compounds of the



formula,

, and hydrogenation in the presence of catalyst to from the final



products

 Dependent claims 2-11, 13-15 and 45-51 are also rejected along with claims 1 and 12 under the judicially created doctrine of obviousness-type double

patenting.

The motivation to make the claimed processes derives from the expectation that the instant claimed processes derived from known Werpy et al. processes would possess similar yields to that which is claimed in the reference.

Claim Objections

- 10. Claims 1-15 and 45-51 are objected to as containing non-elected subject matter, i.e., the variable R_1 containing more than three carbon atoms. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.
- **11**. Claim 51 is objected. It appears there is a typographic error of the term "of" in line 2 of claim 51. Replacement to f the term "of" with a term "or", would obviate the objection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Supervisory Patent Examiner

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Robert Shiao, Ph.D. Patent Examiner Art Unit 1626

February 09, 2006